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09/844,144

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Gary A. Goetzke

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MEDTRONIC, INC.

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EXAMINER

GOTTSCHALK, MARTIN A

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,144

Applicant(s)

GOETZKE ET AL.

Examiner

Martin A. Gottschalk

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 29-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/01/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

04

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-28 in the reply filed on 09/28/2005 is acknowledged.
2. This application contains claims 29-30 drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- A. Claims 2-8 are rejected under the second paragraph of 35 U.S.C. 112. Claim 2 recites the limitation "chronic pain forecasting model". There is insufficient antecedent basis for this limitation in the claim. For the purpose of examination and from the context provided by claim 1, the Examiner will consider this phrase to read "chronic pain care model". Claims 3-8 depend from claim 2, and are thus rejected on the same basis.

Art Unit: 3626

B. Claim 3 is rejected under the second paragraph of 35 U.S.C. 112. Claim 3 recites the limitation "chronic pain forecasting inference engine". There is insufficient antecedent basis for this limitation in the claim. For the purpose of examination and from the context provided by claim 2, the Examiner will consider this phrase to read "chronic pain inference engine".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 9-22, and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Iliff (US Pat# 6,234,964, hereinafter Iliff).

A. As per claim 1, Iliff discloses a method for creating a chronic (Iliff: col 12, Ins 53-56, chronic reads on "continuing medical care of a patient"; col 38, Ins 15-16) pain (Iliff: section titled "PQRST Array", col 33, In 37 to col 35, In 48) patient care plan (Iliff: sections on therapy optimization and adjustment, col 23, In 9 to col 28, In 2), comprising:

Art Unit: 3626

a) selecting direct medical indicia associated with chronic pain that serve as independent variables (Iloff: col 33, lns 54-56);

b) selecting indirect medical indicia associated with chronic pain that serve as independent variables (Iloff: col 14, lns 10-13, indirect medical indicia reads on “patient’s medical history”, which provide the independent variables which establish “...health parameters that are to be measured...”);

c) selecting non-medical indicia associated with chronic pain that serve as independent variables (Iloff: col 11, lns 1-16, reads on “age”);

d) selecting a chronic pain indication that serves as a dependent variable (Iloff: col 14, lns 27-29; col 33, lns 47-50);

e) creating a chronic pain care model using direct medical indicia, indirect medical indicia, non-medical indicia, and chronic pain indication;

f) applying the chronic pain care model to a chronic pain patient to create a patient mathematical expression (applies to steps e and f, Iliff: col 33, entire section entitled “PQRST Array”, where PQRST array is read on by model and mathematical expression; in particular note col 34, lns 17-28

Art Unit: 3626

which discloses that the encoding in the array is “extensible” to include a plurality of aspects associated with pain.)

g) creating a chronic pain patient care plan by comparing each patient mathematical expression to selection objectives (Iloff: col 14, Ins 40-49).

B. As per claim 2, Iliff discloses the method as in claim 1 wherein the chronic pain forecasting model comprises

(a) a logic structure to define a logical decision process to operate on the independent variables and to progressively reach greater certainty about the chronic pain patient care plan (Iloff: col 33, Ins 47-50, logic structure reads on “...a set of software processes...”);

(b) weighted variables to reflect greater relevance of certain direct medical indicia, indirect medical indicia, and non-medical indicia to the chronic pain indication (Iloff: col 17, Ins 31-61, section entitled “Severity Assessment”. The Examiner considers a “patients ranking” to be a form of weighting.); and,

(c) equations that represent relationships between or among weighted variables to form a chronic pain inference engine (Iloff: col 18, Ins 45-66. The Examiner considers the cited plotting of data points, as well as

“standard statistical normalization and curve-fitting techniques” to be forms of relating variables by equations.).

C. As per claim 9, Iliff discloses the method as in claim 1 wherein

the chronic pain patient's care plan is identified with a patient mathematical expression generated by the chronic pain inference engine operating on the patient indicia and the chronic pain indication (rejected for the same reasons as provided above for claims 1 and 2).

D. As per claim 10, Iliff discloses the method as in claim 1 wherein

the patient indicia are monitored for changes and
the patient mathematical expression is updated when patient indicia change (Iliff: col 13: lns 17-22).

E. As per claim 11, Iliff discloses the method as in claim 1 further comprising,

establishing categorization preferences that specify care plan characteristics that are desired to be selected (Iliff: col 13 lns 1-11, i.e. the category is treatment; a care plan characteristic is for example, the specific treatment; and categorization preferences reads on “patient's preferences in treatment”);

calculating the categorization preferences with each chronic pain patient's mathematical expression to identify relationships between the categorization preferences and each potential chronic pain patient's mathematical expression (Iliff: col 25, Ins 4-7, "computes" read on by calculating, mathematical expression reads on "SOCF"); and,

categorizing care plan characteristics based upon the relationships between the categorization preferences and each chronic pain patient's mathematical expression (Iliff: col 25: Ins 54 to col 26, In 4, a care plan characteristic is for example drug dose; treatment based on "high" or "low" SOCF relates treatment preferences to SOCF. Thus based on the relationship between SOCF and patient treatment preference, the dose can be increased or otherwise adjusted.)

F. As per claims 12 and 13, Iliff discloses the method as in claim 11 and 12 respectively, further comprising,

(claim 12) considering each chronic pain patient based upon lifestyle choices to adjust categorization.

(claim 13) wherein lifestyle choices are selected from the group consisting of

Art Unit: 3626

smoking (for both claims 12 and 13, Iliff: col 42, Ins 10-29 reads on “smoking history”, where smoking history is considered to adjust the likelihood of adopting a particular therapy),

alcohol consumption,

obesity,

job choice,

activity level,

sporting activities,

seatbelt use, and

helmet use.

G. As per claim 14, Iliff discloses the method as in claim 1 wherein the selection objectives are selected from the group consisting of

treatment time period,

experimental procedures,

invasive procedures,

back-to-work date,

standard of care (Iliff: col 25, Ins 25-44, reads on “TAPL setting”, see also col 37, Ins 28-35),

Art Unit: 3626

case manager for care, and

treatment provider names.

H. As per claim 15, Iliff discloses the method as in claim 1 wherein

the direct medical indicia are related to chronic pain in a known medical manner and recorded by a clinician (Iliff: col 43, lns 1-6).

I. As per claim 16, Iliff discloses the method as in claim 15 wherein

the direct medical indicia are independent variables selected from the group consisting of

primary diagnosis,

associated secondary diagnosis,

co-morbidities,

drug treatment regimen (col 23, lns 30-65),

telephone consultations with a clinician,

trauma episodes (Iliff: col 37, lns 45-50),

Art Unit: 3626

palliative care,
rehabilitative care,
clinician office visits,
emergency room visits, and
hospitalizations.

J. As per claim 17, Iliff discloses the method as in claim 15 wherein the sources for direct medical indicia are selected from the group consisting of

claims records,

medical records (Iliff: col 11, ln 61 to col 12 ln 1; col 14, lns 9-16),

workers' compensation records, and

employer records.

K. As per claims 18 and 19, Iliff discloses the method as in claim 1 wherein indirect medical indicia are

(claim 18) a chronic pain co-morbidity that is recorded by a clinician (Iliff: col 12, lns 12-14, reads on "diagnosed as HIV positive". The Examiner considers this to be a form of co-morbidity associated with the presenting problem, and that it would have been recorded by a clinician upon original diagnosis.);

Art Unit: 3626

and

(claim 19) independent variables selected from the group consisting of
mental health condition,

acute respiratory episodes (Iliff: col 38, ln 35),

diabetes, and

heart failure.

L. As per claim 20, Iliff discloses the method as in claim 18 wherein the sources for indirect medical indicia are selected from the group consisting of claims records, medical records, workers' compensation records, employer records, and patient surveys (rejected as per claim 17).

M. As per claim 21, Iliff discloses the method as in claim 1 wherein the non-medical indicia are independent variables selected from the group consisting of

pain perception factors (Iliff: col 34, lns 1-9, reads on "...patient's report of pain..."),

Art Unit: 3626

life satisfaction measures, patient support structure, day-time distractions, marital relationship quality, and job satisfaction.

N. As per claim 22, Iliff discloses the method as in claim 21 wherein

the sources for non-medical indicia are selected from the group consisting of

medical records (Iliff: col 11, ln 61 to col 12 ln 1; col 14, lns 9-16),

patient surveys, patient self-reports, employer databases, workers' compensation records, medical chart reviews, patient interviews, treating clinician interviews, and family member interviews.

O. As per claim 25, Iliff discloses the method as in claim 1 wherein the chronic pain patients are selected from the group consisting of

payer database,

employer database,

clinician database (Iliff: Fig. 2, items 240 to 254), and

Art Unit: 3626

workers' compensation database.

P. As per claim 26, the recited steps correspond to steps in claims 1, 2, 10, and 11 above and are thus rejected for the same reasons as provided for these claims. The particular correspondence is as follows:

The first three steps of claim 26 corresponds to claim 1, and claim 2.

The fourth through sixth steps of claim 26 correspond to claim 11.

The last step of claim 26 corresponds to claim 10.

Q. As per claims 27 and 28, they are article of manufacture claim which repeats the same limitations of claims 1 2, 10 and 11, the corresponding method claims, as a collection of executable instructions stored on computer readable media as opposed to a series of process steps. Since the teachings of Iliff disclose the underlying process steps that constitute the method of claims 1, 2, 10, and 11, it is respectfully submitted that they likewise disclose the executable instructions that perform the steps as well. As such, the limitations of claims 27 and 28 are rejected for the same reasons given above for claims 1, 2, 10, and 11. The particular correspondence of the claims is as follows:

Claim 27 corresponds to claims 1 and 2.

Claim 28 corresponds to claims 10 and 11.

Art Unit: 3626

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff as applied to claim 2 above.

A. As per claim 3, although Iliff discloses a method incorporating the use of a plurality of variables and equations (see rejections above for claims 1 and 2), Iliff fails to explicitly disclose the method as in claim 2 wherein the chronic pain forecasting inference engine comprises,

at least fifty dependent variables,

at least thirty independent variables and,

at least fifty equations.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Iliff to allow for any number of variables and equations that the inventor desired as a matter of design choice. *In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

9. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff as applied to claim 2 above, and further in view of Haughton et al (Haughton, D., and Oulabi, S., "Direct Marketing Modeling with CART and CHAID", J. Direct Marketing, v11-4, Fall, 1997, pgs. 42-52. Hereinafter Haughton.).

A. As per claims 4 and 5, Iliff fails to disclose the recited limitations, however, these features are well known in the art as evidenced by the teachings of Haughton, who discloses

the method as in claim 2 wherein the logic structure is developed using

(claim 4) Chi-Square Automatic Interaction Detection (CHAID) (Haughton: pg 44, col 1, section 2, second paragraph)

and

Art Unit: 3626

(claim 5) Classification Adjusted Regression Tree (CART) analysis

(Haughton: pg 44, col 2)

to establish relationships between the dependent variable and the independent variables.

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teachings of Haughton within the method taught by Iliff with the motivation of avoiding the problems of 1) selecting relevant variables from among a large number of possible variables, and 2) manually detecting the possible interactions between the variables (Haughton, pg 43, col 1, second paragraph).

B. As per claims 6 and 7, Iliff fails to disclose the recited limitations, however, these features are well known in the art as evidenced by the teachings of Haughton, who discloses

the method as in claim 2 wherein the weighted variables are developed using

(claim 6) logistical regression

and

(claim 7) discriminate analysis (Haughton: pg 43, col 1, second paragraph for both claims 6 and 7)

to establish relationships between the dependent variable and independent variables.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff as applied to claim 2 above, and further in view of Pollack (US Pat# 5,809,477, hereinafter Pollack).

A. As per claim 8, Iliff fails to disclose the method as in claim 2 wherein

appropriateness of patient indicia is evaluated using the Hosmer-Lemeshow⁵ Goodness of Fit Analysis.

However, this feature is well known in the art as evidenced by teachings of Pollack (Pollack: col 2, lns 1-19).

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teaching of Pollack with the method of Iliff with the motivation of assessing goodness of fit of patient data (Pollack: col 2, lns 1-6).

11. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff as applied to claim 1 above, and further in view of Lederhaas (Lederhaas, G., "Complex Regional Pain Syndrome: New Definitions,

Art Unit: 3626

New Emphasis." Emergency Medicine. New York: Sep 2000. Vol. 32, Iss. 9; pgs 18-21. Hereinafter Lederhaas. Note, the citations provided for this reference may refer to pages 1 through 4, and are referring to the numerals printed by the Examiner in the upper right hand corner of the pages of the enclosed copy of the reference.).

A. As per claims 23 and 24, Iliff fails to disclose the limitations of the claim, however, these features are well known in the art as evidenced by the teachings of Lederhaas.

Lederhaas discloses

(claim 23) the method as in claim 1 wherein the chronic pain indication is selected from the group consisting of

Peripheral Neuropathy; Stump Pain; Phantom Pain;

Complex Regional Pain Syndrome Type I (Reflex Sympathetic Dystrophy); Complex Regional Pain Syndrome Type II (Causalgia) (Lederhaas: pg 1, paragraph 1);

Central Pain; Rheumatoid Arthritis; Osteoarthritis; Sickle Cell Arthropathy; Stiff Man Syndrome; Osteoporosis; Guillain-Barre

Art Unit: 3626

Syndrome; Superior Pulmonary Sulcus Syndrome (Pancoast Tumor); Pain of Skeletal Metastatic Disease of the Neck, Arm, or Shoulder Girdle; Carcinoma of Thyroid; Post Herpetic Neuralgia; Syphilis (Tabes Dorsalis and Hypertrophic Pachymeningitis); Primary Tumor of a Vertebral Body; Radicular Pain Attributable to a Prolapsed Cervical Disk; Traumatic Avulsion of Nerve Roots; Primary Tumor of a Vertegral Body; Radicular Pain Attributable to a Thoracic Disk; Chemical Irritation of the Brachial Plexus; Traumatic Avulsion of the Brachial Plexus; Postradiation Pain of the Brachial Plexus; Painful Arms and Moving Fingers; Brachial Neuritis (Brachial Neuropathy, Neuralgic Amyotrophy, Parsonage-Turner Syndrome); Raynaud's Disease; Raynaud's Phenomenon; Frostbite and Cold Injury; Brythema Pernio (Chilblains); Acrocyanosis; Livedo Reticularis; Volkmann's Ischemic Contracture; Thromboangiitis; Intermittent Claudication; Rest Pain; Gangrene Due to Arterial Insufficiency; Other Postinfectious and Segmental Peripheral Neuralgia; Angina Pectoris; Postmastectomy Pain Syndrome (Chronic Noumalignant); Late Postmastectomy Pain or Regional Carcinoma; Segmental or Intercostal Neuralgia; Chronic Pelvic Pain Without Obvious Pathology; Pain from Urinary Tract; Carcinoma of the Bladder; Lumbar Spinal or Radicular Pain after Failed Spinal Surgery; Spinal Stenosis (Cauda Equina Lesion); Pain referred from Abdominal or Pelvic Viscera or Vessels

Art Unit: 3626

Perceived as Sacral Spinal Pain; Femoral Neuralgia; and, Sciatica Neuralgia.

and

(claim 24) the method as in claim 23 wherein

the source for chronic pain indications is the International Association for the Study of Pain (IASP) chronic pain guidelines (Lederhaas: pg 1, paragraph 1).

For both claims 23 and 24, it would have been obvious at the time of the invention to one of ordinary skill in the art to combine the method of Iliff with the teachings of Lederhass with the motivation of to bring a more organized approach to the treatment of pain (Lederhaas: pg 1, paragraph 2).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art (US Pat# 5,517,405) discloses a knowledge-based system for providing broad-based medical diagnoses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone

Art Unit: 3626

number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MG
01/18/2005



C. LUKE GILLIGAN
PATENT EXAMINER